SE 10/1/01

EXHIBIT A

K 003372

510(k) Summary
Codman BACTISEAL™ Catheters
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

Contact Person

James M. Flaherty, Jr., RAC
Regulatory Affairs Specialist
Telephone Number: (508) 880-8404
Fax Number: (508) 828-3212

Name of Device

Proprietary Name: Codman BACTISEAL™ Catheters
Common Name: Hydrocephalus catheters
Classification Name: Central Nervous System Fluid Shunt and Components

Device Classification

Central nervous system fluid shunts and components are Class II devices per 21 CFR § 888.5550 (84 JXG).

Statement of Substantial Equivalence

Codman BACTISEAL™ Catheters are substantially equivalent to CODMAN®-MEDOS® Ventricular and Peritoneal Catheters based on the subject device's similarity to the predicate devices in intended use, materials, design, and dimensions.

Indications for Use

Codman BACTISEAL™ Catheters are intended for use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid (CSF) is indicated.

Physical Description

Codman BACTISEAL™ Catheters are manufactured from radiopaque silicone rubber which is impregnated with Clindamycin Hydrochloride and Rifampicin in order to render the device resistant to colonization of most gram positive organisms.

Device Testing

Safety of this device to predicate products relied on extensive performance and *in vitro* testing, biocompatibility studies in accordance with ISO10993-Part 1, and clinical data. All testing results demonstrated the substantial equivalence of the product to commercially distributed devices for the same intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2001

Ms. Diane Minear, RAC
Director, Regulatory Affairs
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K003322
Trade/Device Name: Codman BACTISEAL™ Catheter
Regulation Number: 21 CFR 882.4100
Regulation Name: Ventricular Catheter
Regulatory Class: Class II
Product Code: HCA
Dated: June 28, 2001
Received: July 3, 2001

Dear Ms. Minear:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MD

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K003322

Device Name **Codman BACTISEAL™ Catheters**

Indications For Use:

Codman BACTISEAL™ Catheters are intended for use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid (CSF) is indicated.

(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003322

Prescription Use X OR Over-the-Counter Use_____
(Per 21 CFR §801.109)

(Optional Format 1-2-96)